INSTRUCTIONS FOR USE

GLIMATINE 400 mg film-coated tablet

For oral use.

- ***Active ingredient:*** Each film-coated tablet contains 478 mg of Imatinib mesylate equivalent to 400 mg of Imatinib as active ingredient.
- ***Excipients:*** Microcrystalline cellulose Type 101, microcrystalline cellulose Type 102, crospovidone, hydroxypropyl methylcellulose, colloidal silicon dioxide, magnesium stearate, Opadry II Orange 85F230022 (polyvinyl alcohol, polyethylene glycol/macrogol, yellow iron oxide (E172), talc, titanium dioxide (E171), red iron oxide (E172))

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not pass it on to others.*
- *During your treatment with this medicine, tell your doctor that you are using this medicine when you go to a doctor or hospital.*
- *Follow the instructions in this leaflet exactly. Do not use **high or low** doses other than the recommended dose for the medicine.*

In this Leaflet:

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are included.

1. What is GLIMATINE and what is it used for?

GLIMATINE is supplied in packages containing 30 film-coated tablets. Each film-coated tablet contains 400 mg of Imatinib.

GLIMATINE is a medicine containing the active substance called imatinib. This medicine works by inhibiting the growth of abnormal cells in the diseases listed below. These include certain types of cancer.

GLIMATINE is a treatment for adults and children for the following:

- Chronic myeloid leukemia (CML): Leukemia is cancer of the white blood cells. These white cells normally help the body fight infection. Chronic myeloid leukemia is a form of leukemia where certain abnormal white cells (called Myeloid cells) start to grow out of control.
- Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL): Leukemia is cancer of the white blood cells. These white cells normally help the body fight infection. Acute lymphoblastic leukemia is a form of leukemia where certain abnormal white cells (called Lymphoblasts) start to grow out of control. GLIMATINE stops the growth of these cells.

GLIMATINE is also a treatment for adults for the following:

Myelodysplastic/myeloproliferative diseases (MDS/MPD): These are a group of blood diseases where some blood cells start to grow out of control. GLIMATINE stops the growth of these cells in a specific subtype of these

diseases.

Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL): These are blood diseases where some blood cells (called eosinophils) start to grow out of control. GLIMATINE stops the growth of these cells in a specific subtype of these diseases.

- **Gastrointestinal stromal tumors (GIST):** GIST is cancer of the stomach and intestines. This originates from uncontrolled cell growth of the supporting tissues of these organs.

Dermatofibrosarcoma protuberans (DFSP): DFSP is a cancer of the tissue beneath the skin where some cells start to grow out of control. GLIMATINE stops the growth of these cells.

If you have any questions about how GLIMATINE works or why this medicine has been given to you, ask your doctor.

2. What you need to know before you use GLIMATINE

GLIMATINE should only be prescribed to you by a doctor experienced in the medicines used in your treatment.

Carefully follow all instructions from your doctor, even if they differ from the general information contained in this leaflet.

Do NOT use GLIMATINE in the following situations

If:

- You are allergic (hypersensitive) to imatinib or to any of the excipients listed at the beginning of this leaflet.

If this applies to you, **tell your doctor before taking GLIMATINE.**

If you think you might be allergic but are not sure, ask your doctor for advice.

Use GLIMATINE CAREFULLY in the following situations

If;

- You have or have had a problem with your liver, kidneys or heart.
- You are receiving levothyroxine therapy because your thyroid has been removed.
- If you have had a hepatitis B infection or there is a possibility that you have hepatitis B now. This is because GLIMATINE can cause reactivation of hepatitis B infection, which can be fatal in some cases. Before starting treatment, patients will be carefully checked by their doctor for signs of this infection.
- If you experience bruising, bleeding, fever, fatigue and confusion while taking GLIMATINE, tell your doctor. These may indicate damage to blood vessels, known as thrombotic microangiopathy (TMA).

If any of these apply to you, tell your doctor before taking GLIMATINE.

You may become more sensitive to the sun while taking GLIMATINE. It is important to cover sun-exposed areas of your skin and use sunscreens with a high sun protection factor (SPF). These precautions also apply to children.

Contact your doctor immediately if you gain weight very quickly during GLIMATINE treatment. GLIMATINE can cause your body to retain water (severe fluid retention).

Your doctor will regularly check whether the medicine is working while you are taking GLIMATINE. You will also need to have regular blood tests and be weighed.

GLIMATINE is also a treatment for children with CML. There is no experience in children with CML under 2 years of age. There is limited experience in children with Ph-positive ALL and very limited experience in children with MDS/MPD, DFSP, GIST and HES/CEL.

Growth may be slower than normal in some children and adolescents taking GLIMATINE. The doctor will monitor growth during regular visits.

Using GLIMATINE with food and drink

Swallow GLIMATINE tablets whole with food and a large glass of water.

If you cannot swallow the tablets, you can mix them with a glass of water or apple juice.

Pregnancy

Consult your doctor or pharmacist before using the medicine.

Tell your doctor if you are pregnant or think you might be pregnant. GLIMATINE should not be used during pregnancy unless absolutely necessary, as it may harm your baby.

Your doctor will explain the potential risk of using GLIMATINE during pregnancy.

Women who can become pregnant are advised to use a highly effective method of contraception during treatment and for 15 days after stopping treatment.

If you discover that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breastfeeding

Consult your doctor or pharmacist before using the medicine.

Tell your doctor if you are breastfeeding your baby. Do not breastfeed your baby while being treated with GLIMATINE and for 15 days after stopping treatment, as it may harm your baby.

Patients concerned about their fertility while using GLIMATINE are advised to consult their doctor.

Driving and using machines

When using GLIMATINE, you may feel dizzy or drowsy, or your vision may become blurred. In such a case, do not drive or use any tools or machines until you feel well again.

Important information about some of the excipients in GLIMATINE

There are no excipients requiring warnings.

Using with other medicines

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including over-the-counter medicines (such as paracetamol) and herbal medicines (such as St. John's wort). Some medicines may interfere with the effect of GLIMATINE when taken together. They can increase or decrease the effect of GLIMATINE, leading to increased side effects or GLIMATINE being less effective. GLIMATINE may also have the same effect on some medicines.

Tell your doctor if you are taking medicines that prevent blood clot formation.

3. How to use GLIMATINE?

Instructions for proper use and dose / frequency of administration:

Always use GLIMATINE exactly as your doctor has told you. Check with your doctor if you are not sure.

Use in adults

Your doctor will tell you exactly how many GLIMATINE tablets to take.

- **If you are being treated for CML:**

Depending on your condition, the usual starting dose is 400 mg or 600 mg **once daily**.

If you are being treated for GIST:

The starting dose is 400 mg **once daily**.

For CML and GIST, your doctor may prescribe a higher or lower dose depending on how you respond to treatment. If your daily dose is 800 mg, you should take 400 mg in the morning and 400 mg in the evening.

If you are being treated for Ph-positive ALL:

The starting dose is 600 mg **once daily**.

- **If you are being treated for MDS/MPD:**

The starting dose is 400 mg **once daily**.

- **If you are being treated for HES/CEL:**

The starting dose is 100 mg **once daily**. Depending on how you respond to treatment, your doctor may decide to increase the dose to 400 mg **once daily**.

- **If you are being treated for DFSP:**

The dose is 800 mg daily, taken as 400 mg in the morning and 400 mg in the evening.

A dose of 400 mg can be taken as 1 tablet of 400 mg or 4 tablets of 100 mg.

A dose of 600 mg can be taken as 1 tablet of 400 mg plus 2 tablets of 100 mg.

Route and method of administration:

Take GLIMATINE with food; this will help protect your stomach.

Swallow the tablets whole with a large glass of water.

If you cannot swallow the tablets, you can dissolve them in a glass of water or apple juice:

- Use about 50 ml for every 100 mg tablet, or 200 ml for every 400 mg tablet.
- Stir with a spoon until the tablets are completely dissolved.
- Once the tablet is dissolved, drink the contents of the glass completely and immediately. Traces of dissolved tablets may remain in the glass.

Different age groups:

Use in children and adolescents:

Your doctor will tell you how many GLIMATINE tablets your child needs for treatment. The amount of GLIMATINE your child should use will be calculated considering their condition, body weight, and height. The total daily dose should not exceed 800 mg in children treated for CML and 600 mg in Ph+ ALL. The daily treatment dose for your child can be given as a single dose per day or divided into two doses, half in the morning and half in the evening.

Use in the elderly:

GLIMATINE can be used in people over 65 years of age at the same dose as other adults.

Special use cases:

Kidney/Liver insufficiency:

Patients with renal dysfunction or dialysis patients should be given the recommended minimum daily dose of 400 mg as an initial dose. However, caution is advised in these patients. If not tolerated, the dose may be reduced. If tolerated, the dose may be increased for ineffectiveness.

GLIMATINE is primarily metabolized (undergoes chemical change) by the liver. Patients with mild, moderate or severe hepatic dysfunction should be given the lowest recommended dose of 400 mg daily. The dose may be reduced if not tolerated. Follow these instructions unless your doctor gives you a different recommendation.

Do not forget to take your medicine on time.

Your doctor will tell you how long your treatment with GLIMATINE will last. Do not stop treatment early, as you may not get the desired result.

If you have the impression that the effect of GLIMATINE is too strong or too weak, talk to your doctor or pharmacist.

If you use more GLIMATINE than you should:

If you have used more GLIMATINE than you should, talk to a doctor or pharmacist. You may need medical treatment.

If you forget to use GLIMATINE:

If you miss a dose or vomit, do not repeat the dose. Take your next dose as planned.

Do not take a double dose to make up for forgotten doses.

Effects that may occur when treatment with GLIMATINE is stopped

Stopping GLIMATINE treatment can make your illness worse. Do not stop using GLIMATINE unless directed by your doctor. If you have any questions about the use of GLIMATINE, ask your doctor or pharmacist.

4. What are the possible side effects?

Like all medicines, GLIMATINE can cause side effects in people sensitive to the substances contained in it.

Side effects are listed as shown in the categories below:

Very common :May be seen in at least 1 in 10 patients.
Common :May be seen in less than 1 in 10 patients, but more than 1 in 100 patients.
Uncommon :May be seen in less than 1 in 100 patients, but more than 1 in 1,000 patients.
Rare :May be seen in less than 1 in 1,000 patients, but more than 1 in 10,000 patients.
Very rare :May be seen in less than 1 in 10,000 patients.
Not known :Cannot be estimated from the available data.

Some side effects can be serious. Tell your doctor immediately if you experience any of the following:

If any of the following occur, stop using GLIMATINE and IMMEDIATELY inform your doctor or go to the emergency department of the nearest hospital:

- A type of allergic reaction (anaphylaxis) causing difficulty swallowing or breathing, swelling and tingling, which may be accompanied by a drop in blood pressure with dizziness or loss of consciousness.
- A hypersensitivity reaction to the drug characterized by fever, skin rash and internal organ involvement (DRESS).
- Severe skin reaction (toxic epidermal necrolysis (TEN)) which may be accompanied by any of the following symptoms: skin rash, reddening of the skin, blisters on the lips, eyes or mouth, peeling of the skin, high fever, flu-like symptoms and enlarged lymph nodes.

These are all very serious side effects.

If you have any of these, it means you have a severe allergy to GLIMATINE. You may need urgent medical attention or hospitalization.

Very common or common:

- Rapid increase in body weight. GLIMATINE can cause your body to retain water (severe fluid retention).
- Signs of infection such as fever, severe chills, sore throat or mouth ulcers. GLIMATINE can reduce the number of white blood cells, so you may get infections more easily.
- Unexpected bleeding or bruising (when you are not injured).

Uncommon or rare:

- Chest pain, irregular heart rhythm (signs of heart-related problems).
- Cough, difficulty breathing or painful breathing (signs of lung-related problems).
- Dizziness, feeling lightheaded or fainting (signs of low blood pressure).
- Nausea with loss of appetite, dark urine, yellow skin or eyes (signs of liver-related problems).
- Rash, red skin with blisters on the lips, eyes, skin or mouth, peeling skin, fever, raised red or purple spots on the skin, itching, burning sensation, skin rash with blisters (signs of skin-related problems).
- Severe abdominal pain, blood in your vomit, stool or urine, black stool (signs of gastrointestinal problems).
- Severe reduction in urine output, feeling thirsty (signs of kidney-related problems).
- Nausea with diarrhea and vomiting, abdominal pain or fever (signs of bowel-related problems).
- Severe headache, weakness, paralysis in limbs or face, difficulty speaking, sudden loss of consciousness (signs of nervous system-related problems such as bleeding or swelling in the skull/brain).
- Pale skin, feeling tired and shortness of breath and dark urine (signs of low red blood cell levels).
- Eye pain or impaired vision, bleeding in the eyes.
- Bone or joint pain (signs of osteonecrosis).
- Blisters on the skin or mucous membrane (signs of pemphigus).
- Numbness or coldness in fingers and toes (signs of Raynaud's syndrome).
- Sudden swelling and redness of the skin (signs of a skin infection called cellulitis).
- Difficulty hearing.
- Muscle weakness and spasms, accompanied by abnormal heart rhythm (signs of changes in the amount of potassium in your blood).
- Bruising.
- Stomach pain accompanied by nausea.
- Muscle spasms with fever, red-brown urine, pain or weakness in your muscles (signs of muscle-related problems).

- Pelvic pain with unexpected vaginal bleeding, sometimes accompanied by nausea and vomiting, feeling dizzy or fainting due to low blood pressure (signs of problems with your ovaries or uterus).
- Nausea, shortness of breath, irregular pulse, cloudy urine, fatigue and/or joint discomfort, accompanied by abnormal test results (e.g., high potassium, uric acid and calcium levels and low phosphorus levels in the blood).
- Blood clots in small blood vessels (thrombotic microangiopathy).

Not known:

- Widespread severe rash, nausea, fever, high levels of certain white blood cells or jaundice (signs of jaundice) with shortness of breath, chest pain/discomfort, severely reduced urine output and feeling thirsty, etc. (combination of signs of treatment-related allergic reaction).
- Chronic kidney failure.
- Reactivation of hepatitis B infection if you have had hepatitis B (a liver infection) in the past.

Other side effects may include:

Very common:

- Headache or feeling tired.
- Nausea, vomiting, diarrhea or indigestion.
- Skin rash.
- Musculoskeletal pain, including muscle cramps or joint, muscle or bone pain during GLIMATINE treatment or after stopping GLIMATINE.
- Swelling, such as around your ankles or swelling of the eyes.
- Increase in body weight.

Common:

- Loss of appetite (anorexia), weight loss or impaired taste.
- Dizziness or feeling weak.
- Difficulty sleeping (insomnia).
- Eye discharge with itching, redness and swelling (conjunctivitis), watery eyes or blurred vision.
- Nosebleeds.
- Abdominal pain or swelling, gas, heartburn or constipation.
- Itching.
- Unusual hair loss or thinning.
- Numbness of hands or feet.
- Mouth ulcers.
- Joint pain with swelling.
- Dry mouth, dry skin or dry eyes.
- Decreased or increased skin sensitivity.
- Hot flashes, chills or night sweats.

Uncommon:

- Painful red lumps on the skin, skin pain, skin redness (inflammation of the fatty tissue under the skin).
- Cough, runny or stuffy nose, feeling of pressure or pain when pressed on the area above the eyes or on the sides of the nose, nasal congestion, sneezing, sore throat, with or without headache (signs of upper respiratory tract infection).
- Severe headache, usually felt as a throbbing pain or pulse on one side of the head, and often accompanied by nausea, vomiting and sensitivity to light or sound (signs of migraine).
- Flu-like symptoms (influenza).
- Pain or burning sensation when urinating, increased body temperature, pain in the groin or pelvic area, red or brown colored or cloudy urine (signs of urinary tract infection).

- Joint pain and swelling (signs of arthralgia).
- A persistent feeling of sadness and loss of interest that prevents you from performing your normal activities (signs of depression).
- Feelings of anxiety and worry with physical symptoms such as palpitations, sweating, tremors, dry mouth (signs of anxiety).
- Drowsiness/lethargy/excessive sleep.
- Tremors or shaky movements (tremor).
- Memory impairment.
- Irresistible urge to move legs (restless legs syndrome).
- Hearing sounds without an external source in the ears (e.g., ringing, buzzing) (tinnitus).
- High blood pressure (hypertension).
- Belching.
- Inflammation of the lips.
- Difficulty swallowing.
- Increased sweating.
- Skin discoloration.
- Brittle nails.
- Red lumps or white-headed pimples around the hair follicles, possibly with pain, itching or a burning sensation (signs of inflammation of the hair follicles, also called folliculitis).
- Skin rash with scaling or peeling (exfoliative dermatitis).
- Breast enlargement (can occur in men or women).
- Mild pain and/or feeling of heaviness in the testicles or lower abdomen, pain when urinating, pain during sexual intercourse or ejaculation, blood in the urine (signs of edema in the testicles).
- Inability to maintain or achieve an erection (erectile dysfunction).
- Heavy or irregular menstrual periods.
- Difficulty in achieving/maintaining sexual arousal.
- Decreased sexual desire.
- Nipple pain.
- Generally feeling unwell (malaise).
- Viral infection such as a common cold.
- Back pain caused by kidney disorder.
- Increased frequency of urination.
- Increased appetite.
- Pain or burning sensation in the upper abdomen and/or chest (heartburn), nausea, vomiting, acid reflux, feeling of fullness and bloating, black stools (signs of stomach ulcer).
- Joint and muscle stiffness.
- Abnormal laboratory test results.

Rare:

- Confusion.
- Nail discoloration.

Not known:

- Redness and/or swelling in the palms of the hands and soles of the feet, which may be accompanied by numbness and burning pain.
- Slowed growth in children and adolescents.
- Painful and/or blistering skin lesions.

If any of these effects affect you, tell your doctor.

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects directly to the Turkish Pharmacovigilance Centre (TÜFAM) by clicking on the "Drug Side Effect Notification" icon on www.titck.gov.tr, or by calling the side effect notification line at 0 800 314 00 08.

5. How to store GLIMATINE?

Keep GLIMATINE out of the sight and reach of children and in its packaging. Store at room temperature below 25ºC.

Use in accordance with the expiry date.

Do not use GLIMATINE after the expiry date on the packaging.

Do not use GLIMATINE if you notice any defects in the product and/or its packaging. Store in the original packaging to protect from moisture.

Do not dispose of expired or unused medicines in the trash! Give them to the collection system determined by the Ministry of Environment, Urbanization and Climate Change.

Marketing Authorisation Holder ***:*** Tepe İlaç San. ve Tic. Ltd. Şti.
Çankaya/ ANKARA

Manufacturer ***:*** World Medicine İlaç San ve Tic. A.Ş.
Bağcılar / İSTANBUL

This leaflet was approved on 15.09.2026.

You can access detailed and up-to-date information about this medicine by scanning the QR code with a smartphone/tablet or a QR code reader.